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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/391,606	09/07/1999	ANDREW D. MURDIN	1038-971-MIS	8817

7590

08/20/2003

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EXAMINER

CHEN, SHIN LIN

ART UNIT

PAPER NUMBER

1632

22

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/391,606

Applicant(s)

MURDIN ET AL.

Examiner

Shin-Lin Chen

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
2. ☐ The proposed amendment(s) will not be entered because:  
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ they raise the issue of new matter (see Note below);  
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): 35 U.S.C. 112 second paragraph rejection of claims 10 and 11.  
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1,2,4-7 and 9-20.Claim(s) withdrawn from consideration: 3 and 8.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.  
10. ☐ Other: \_\_\_\_\_

Shin-Lin Chen  
Primary Examiner  
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Continuation of 5. does NOT place the application in condition for allowance because: Applicants argue that the specification is addressed to a person skilled in the art and the invention is directed to an immunogenic composition comprising two specific nucleotide sequences encoding known proteins (amendment, p. 5, 6). This is not found persuasive because of the reasons of record. (Continued) .

### DETAILED ACTION

Continued from Advisory Action:

The claims do not specify a particular nucleotide sequence(s) and is given broadest reasonable interpretation in light of the specification. The scope of the claim includes nucleotide sequences encoding a genus of numerous structural variants of the disclosed MOMP or 76 kDa protein, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The claimed nucleotide sequences encompass unknown and unidentified nucleotide sequences encoding MOMP or 76 kDa protein derived from various species and strains of *Chlamydia*. The specification fails to provide the nucleotide sequences encoding those MOMP or 76 kDa proteins derived from various species and strains of *Chlamydia*. Thus, the limited information as disclosed is not sufficient to reasonably convey to one skilled in the art that applicants were in possession of the nucleotide sequences encoding MOMP or 76 kDa proteins derived from various species and strains of *Chlamydia* for the immunogenic composition as claimed.

Applicants argue that the vectors pCAMOMP and pCA76kDa are used as examples to provide protection against *C. Pneumoniae* lung infection in mice, and the claims are directed to an immunogenic composition and not directed to gene therapy *in vivo*. The use of the immunogenic composition is irrelevant (amendment, p. 6). This is not found persuasive because of the reasons of record. As discussed before, the claims are directed to an **immunogenic** composition for *in vivo* administration to a host. Although the claim are not directed to a method

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of immunization, the claimed immunogenic composition must have a use for one skilled in the art at the time of the invention. The use of the **immunogenic** composition is to stimulate immune response in a host so as to immunize the host or provide therapeutic effects against a particular disease, such as Chlamydial infection, in the host in light of the specification (see specification, p. 9 lines 7-11). Therefore, the claims read on gene therapy *in vivo* and the claimed immunogenic composition must have a use for stimulating immune response in a host so as to immunize the host or provide therapeutic effects against a particular disease, such as Chlamydial infection, in the host. Therefore, the use of the claimed immunogenic composition *in vivo* is relevant to the claimed invention.

Applicants argue that it is evident that the composition is used to protect against chlamydial infection but not other diseases (amendment, p. 7). This is not found persuasive because of the reasons of record. The use of the claimed immunogenic composition is not limited to protect against chlamydial infection. Since the claims encompass using various unknown and unidentified nucleotide sequences encoding MOMP or 76 kDa protein derived from various species and strains of *Chlamydia*, it is likely that a MOMP protein or a 76 kDa protein can be used to stimulate immune response in a subject to protect against disease other than chlamydial infection, for example, to inhibit cancer cell growth. Further, the specification fails to provide adequate guidance and evidence for an immunogenic composition containing nucleotide sequences encoding any MOMP and/or 76 kDa protein derived from any species or any strain of *Chlamydia* for *in vivo* administration of any host, including human, mammals, birds, reptiles, fishes etc., to protect the host against a particular disease, such as a Chlamydial infection, other than using the disclosed pCAMOMP and pCA76kDa to protect against *C.*

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*Pneumoniae* lung infection. Therefore, the claims remain rejected under 35 U.S.C. 112 first paragraph.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

